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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/538,245

06/07/2005

David Feifel

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04/04/2008

BUCHANAN, INGERSOLL & ROONEY LLP

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ALEXANDRIA, VA 22313-1404

EXAMINER

DUTT, ADITI

ART UNIT

PAPER NUMBER

1649

NOTIFICATION DATE

DELIVERY MODE

04/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

ADIPFDD@bipc.com

| | | | |
|------------------------------|--------------------------------------|--------------------------------------|--|
| Office Action Summary | Application No. 10/538,245 | Applicant(s) FEIFEL, DAVID | |
| | Examiner Aditi Dutt | Art Unit 1649 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 January 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 15-19, 21-27, 29, 30 and 32-34 is/are pending in the application.
- 4a) Of the above claim(s) 1-10, 19 and 27 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 15-18, 22 and 24-26 is/are allowed.
- 6) ☒ Claim(s) 21, 23, 29, 30 and 32-34 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/3/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of Claims

1. The amendment filed on 3 January 2008 has been entered into the record and has been fully considered. Claims 15-16, 22-24, and 32 have been amended. Claims 1-10, 19, 27 are withdrawn by Applicant to non-elected matter. Claim 31 is cancelled.

Election/Restrictions

2. Applicant's response to previous Office Action in the reply filed on 3 January 2008 is acknowledged. Claims 1-10, 15-19, 21-27, and 29-34 are pending in the instant application.
3. Claims 15-18, 21-26, 29-30, 32-34, drawn to a method for increasing sensorimotor gating or inhibiting serotonin-2A and/or alpha-1 receptor mediated neural function and improving cognitive function by administration of neurotensin agonist to a subject, are being considered for examination in the instant application.
4. Any objection or rejection of record, which is not expressly repeated in this action has been overcome by Applicant's response and withdrawn.
5. Applicant's arguments filed on 3 January 2008, have been fully considered. New grounds of objection and rejection are as follows:

Response to Amendment

Withdrawn objections and/or rejections

6. Declaration

The Declaration submitted by David Feifel under 37 CFR 1.131 filed on 2 January 2008 is sufficient to overcome the rejection of claims 15-18, 22, 24-26 and 31, based upon prior art 102(a). Applicant's submission of the reference by Shilling et al., is acknowledged as added evidence to overcome the above rejection.

Claim rejections/objections maintained/new grounds of rejection

35 USC § 112-Scope of Enablement

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. The rejection of claims 15-18, 21-26, 29-34, are being applied to the amended claims 21, 23, 29-30 and 32-34 for reasons of record in the Office Action dated 3 July 2007 (pages 3-5).

9. Applicant alleges that the rat model having drug induced pre-pulse inhibition (PPI) is a recognized model for schizophrenia and that serotonin-2 receptor blockers serve as therapeutics in psychiatric disorders. Since the instant specification demonstrates that neurotensin agonists like NT69L and PD149163 can reverse the PPI disruption

Art Unit: 1646

induced by serotonin 2A receptor agonist DOI, Applicant believes that this is a novel pharmacological property of the instantly claimed neurotensin agonists. Applicant further clarifies that the claimed methods of treatment do not seek to identify the origin or the pathogenesis of the disease, rather “treat a subject that has the disease, a symptom of which is decreased PPI (a symptom treated by the invention)” (emphasis added by Examiner). Based on the reference relied for art in the previous Office Action, Applicant contends that the claimed invention bears a reasonable correlation to diseases like bipolar disorder and schizophrenia. Applicant finally alleges that the citation of Hedley et al. as a §102 reference proves the instant specification to be an enabling disclosure. Therefore, the allegation of the Office showing that the instant application is non-enabling because PPI in the rat model might bear no relationship with the pathogenesis of disorders like schizophrenia etc., while simultaneously citing the Hedley reference under §102 statute, is improper. Finally, Applicant concludes that the PPI model of the reference and that used in the instant specification are the same, i.e. both are pharmacological models having a “correlation to symptomatic criteria of bipolar, schizophrenia, anxiety and depression”, therefore, if the Office maintains the Hedley et al.’s disclosure as enabling, then Applicant’s disclosure “must also be enabling”. Thus Applicant requests the withdrawal of the rejection.

Art Unit: 1646

10. Applicant's arguments have been fully considered but have been found to be persuasive in part. The Office acknowledges that the citation of Hedley et al. reveals an enabling method for testing the effect of the neurotensin agonist on the reversal of pharmacologically induced PPI in a rat PPI model for schizophrenia, therefore, has partially erred in rejecting the instant disclosure for not enabling the use of the rat PPI model for treating PPI disruptions in subjects with bipolar disorder, schizophrenia and depression. Examiner is, therefore, withdrawing the enablement rejection directed to claims 15-18, 22, 24-26. However, the specification still does not provide enablement for treating a subject having any neuropsychiatric disorder by administration of a pharmaceutical dose of a neurotensin agonist, especially in view of Applicant's own submission, that the claimed method is enabled for treating a symptom of the disease, and that the instant PPI rat model is a pharmacological model that bears correlation to symptomatic criteria of the diseases. As described in the previous Office Action, neuropsychiatric diseases are complex in nature involving various biochemical interactions, resulting in a number of symptoms and pathology, of which PPI is only one symptom. Since the specification acknowledges that patients with neuropsychiatric disorders are treatment refractory, and because the specification does not provide guidance on treating neuropsychiatric diseases (other than treating PPI abnormality), undue experimentation will be required of the skilled artisan to use the PPI model for treating the disease. Likewise, since there is no

Art Unit: 1646

information or indication in the relevant literature that the treatment of PPI will result in the treatment of the entire disease, the claimed methods for treating a subject having any neuropsychiatric disorder, e.g. bipolar disorder, schizophrenia, anxiety disorder, depression, etc. are not enabled and thus stay rejected.

11. Specifically, proper analysis of the Wands factors was provided in the previous Office Action. Due to the large quantity of experimentation necessary to treat a subject having any neuropsychiatric disorder by administering NT69L; lack of direction/guidance presented in the specification regarding the same; the complex nature of the invention; the state of the prior and post art which shows the unpredictability of treatment of neuropsychiatric diseases; undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

New Objections

Claim Objections

12. Claims 21 and 29 objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claims 21 and 29 reciting "neuropsychiatric disorder" fail to limit the subject matter of independent claims 15/16 and

Art Unit: 1646

24 respectively, which recite narrower limitations "bipolar disease.....
depression disease or disorder".

Conclusion

13. Claims 15-18, 22, 24-26 are allowable.

14. **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37
CFR 1.136(a).

15. A shortened statutory period for reply to this final action is set to
expire THREE MONTHS from the mailing date of this action. In the event
a first reply is filed within TWO MONTHS of the mailing date of this final
action and the advisory action is not mailed until after the end of the
THREE-MONTH shortened statutory period, then the shortened statutory
period will expire on the date the advisory action is mailed, and any
extension fee pursuant to 37 CFR 1.136(a) will be calculated from the
mailing date of the advisory action. In no event, however, will the statutory
period for reply expire later than SIX MONTHS from the date of this final
action.

16. Any inquiry concerning this communication or earlier
communications from the examiner should be directed to Aditi Dutt whose
telephone number is (571) 272-9037. The examiner can normally be
reached on Monday through Friday, 9:00 a.m. to 5:00 p.m.

Art Unit: 1646

17. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffrey Stucker, can be reached on (571) 272-0911. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.
18. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov/>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

AD
24 March 2008

/Gary B. Nickol /

Supervisory Patent Examiner, Art Unit 1646

Art Unit: 1646